K120563

MAR 30 2012

510(k) SUMMARY

MICROPHAGE's KeyPath™ MRSA/MSSA Blood Culture Test – BT

MicroPhage, Inc.
2400 Trade Centre Ave.
Longmont, CO 80503

Phone: 303-652-5049
Facsimile: 303-652-5080

Contact Person: Drew Smith, PhD.

Date Prepared: February 24, 2012

Name of Device and Name/Address of Sponsor

KeyPath™ MRSA/MSSA Blood Culture Test – BT

MicroPhage, Inc.
2400 Trade Centre Ave.
Longmont, CO 80503

Common or Usual Name

Methicillin-resistant *Staphylococcus aureus* (MRSA) and Methicillin-susceptible *Staphylococcus aureus* (MSSA) from positive blood culture bottles test

Classification Name

Staphylococcal typing bacteriophage

Regulation

21 C.F.R. § 866.2050

Product Code

OUS

Classification Panel

Microbiology

Predicate Devices

KeyPath™ MRSA/MSSA Blood Culture Test – BT (k102342)

Intended Use / Indications for Use

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is a qualitative *in vitro* diagnostic test for the timely identification of *Staphylococcus aureus (S. aureus)* and determination of methicillin susceptibility (MSSA) or methicillin resistance (MRSA) directly from positive blood cultures.

The Test uses bacteriophage amplification to identify the presence of *S. aureus* and assess the phenotypic response of the target organism to cefoxitin, an indicator of oxacillin (a methicillin analog) resistance.

The assay is performed directly on positive blood culture specimens that are determined as Gram Positive Cocci in singles (GPC) or as Gram Positive Cocci in Clusters (GPCC) by Gram stain.

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is performed directly on positive blood culture specimens from BD BACTEC™ blood culture bottles (Plus Aerobic/F, Plus Anaerobic/F, Standard/10 Aerobic/F and Standard Anaerobic/F).

The Test is indicated for use in conjunction with other laboratory and clinical data available to the physician as an aid in the detection of MRSA/MSSA from positive blood cultures.

Subculturing of positive blood cultures is necessary for additional susceptibility test determinations, differentiation of mixed growth and for epidemiological typing.

Technological Characteristics

The KeyPath™ MRSA/MSSA Blood Culture Test – BT (KeyPath™ Test) is a bacteriophage amplification-enabled immunoassay to identify *Staphylococcus aureus* and determine its resistance or susceptibility to cefoxitin from positive blood cultures, which have been determined to have Gram Positive Cocci in singles (GPC) or Gram Positive Cocci in Clusters (GPCC) by Gram stain. This method utilizes the specificity of bacteriophage/bacteria interactions and their natural amplification processes to produce a surrogate signal. In the presence of *S. aureus,* bacteriophage will replicate, increasing to a detectable concentration. In the absence of *S. aureus* or the presence of bacteria other than *S. aureus,* the KeyPath™ Test bacteriophage do not replicate and remain undetectable. In addition, susceptible strains of *S. aureus* do not grow in the presence of cefoxitin and therefore do not support bacteriophage amplification, while resistant strains will grow and support bacteriophage amplification.

To perform the KeyPath™ Test, a sample of the positive blood culture is added to each of the two provided reaction tubes, each comprised of KeyPath™ Test bacteriophage and proprietary reagents that enhance the growth of *S. aureus* and suppress other organisms. One Reaction Tube (Blue) is used for *S. aureus* identification. The second Reaction Tube (Red) is used for resistance/susceptibility testing. Following incubation, a small amount of the sample from each Tube is pipetted onto corresponding sample wells on the Detector. If the specimen contains *S. aureus* a pink-to-dark red/ purple Test Line (T) will appear in the Blue ID Window of the Detector.

If the sample is positive for *S. aureus,* Resistance/Susceptibility is then determined by reading the Red RS Window. Resistance (MRSA) is determined by the development of a visible pink-to-dark red/purple line at the Test Line (T) in the Red RS Window, while Susceptibility (MSSA) is determined by the absence of a visible colored line at the Test Line (T) in the Red RS Window.

Performance Data

Study Design

The purpose of this submission is to establish equivalent performance of the KeyPath™ MRSA/MSSA Blood Culture Test – BT in additional bottle types, as compared to cleared bottle types. Previously cleared bottle types are BACTEC™ Plus Aerobic/F and Plus Anaerobic/F. The additional bottle types for which clearance is being sought are BACTEC™ Standard /10 Aerobic/F and Standard Anaerobic/F.

A Media Interference Study was performed to demonstrate that blood culture matrix does not act as an interferent in the KeyPath™ Test; and a performance study was performed to demonstrate that the KeyPath™ Test shows ≥ 95% positive and negative agreement for *S. aureus* identification and determination of methicillin resistance.

Media Interference Study

Study description and methods

Performance of the KeyPath™ MRSA/MSSA Blood Culture Test – BT was analyzed in presence of 10 µL (nominal) and 20µL (twice the nominal volume) of blood culture matrix from appropriate bottles. Five replicates of 16 strains (4 MRSA, 4 MSSA and 8 NSA) were tested. For test matrix and positive controls, blood culture bottles containing blood from volunteers were inoculated with approximately 100 CFU of bacteria and grown to alarm in the BACTEC™ 9050. Negative controls were comprised of un-inoculated blood culture mix containing blood. No interference was demonstrated if the correct results for each strain type were observed.

Results and conclusions

Negative controls – For both SA and SN bottles the KeyPath™ Test returned negative results (NSA) in all replicates, as shown in **Tables 6.1** and **6.2**.

Positive controls – For both SA and SN bottles, the KeyPath™ Test returned the expected results in all replicates, as shown in **Tables 6.1** and **6.2**.

Test matrix – For both SA and SN bottles, the KeyPath™ Test returned the expected results in all replicates, as shown in **Tables 6.1** and **6.2**.

Table 6.1 – Summary Data for SA Bottle Interference

Summary data for SA bottle interference

		KP Test Result		
Condition	**Type**	**MRSA**	**MSSA**	**NSA**
Negative Control	None	0	0	20
Control	MRSA	20	0	0
	MSSA	0	20	0
	NSA	0	0	40
Test	MRSA	20	0	0
	MSSA	0	20	0
	NSA	0	0	40

Table 6.2 – Summary Data for SN Bottle Interference

Summary data for SN bottle interference

		KP Test Result		
Condition	**Type**	**MRSA**	**MSSA**	**NSA**
Negative Control	None	0	0	20
Control	MRSA	20	0	0
	MSSA	0	20	0
	NSA	0	0	40
Test	MRSA	20	0	0
	MSSA	0	20	0
	NSA	0	0	40

All test results are as expected. We conclude that blood culture matrix from SA and SN bottles does not interfere with the KeyPath™ MRSA/MSSA Blood Culture Test – BT.

Performance Study

Study description and methods

A panel of ≥ 20 MRSA, ≥ 20 MSSA and ≥ 20 NSA clinical blood culture isolates from unique patients was tested in the KeyPath™ MRSA/MSSA Blood Culture Test – BT.

BACTEC™ Standard/10 Aerobic/F (SA) and Standard Anaerobic/F (SN) bottles were charged with blood from healthy volunteers per IRB-approved study protocol MP2007A. Bottles were inoculated with approximately 100 CFU from fresh overnight cultures.

Testing and external daily controls were performed per Package Insert instructions (181-00005 Rev.A) within 24 hours of alarm. Bottles that did not alarm within 3 days were discarded.

Results and conclusions

Tables 6.3 and **6.4** summarize the SA bottle data for *S. aureus* identification, and determination of resistance and susceptibility within *S. aureus*, respectively. **Tables 6.5** and **6.6** summarize the SN bottle data for *S. aureus* identification, and determination of resistance and susceptibility within *S. aureus*, respectively.

Table 6.3 – *S. aureus* identification summary, SA bottles

Analysis: *S. aureus* Identification

SA bottles

KeyPath	Reference +	Reference -
+	45	0
-	0	35
Total	45	35

Statistic	Percent	95 % CI	
		Lower	Upper
Positive Agreement	100	92.1	100
Negative Agreement	100	90.0	100

Table 6.4 – Resistance summary, SA bottles

Analysis: Methicillin resistance

SA bottles

KeyPath	Reference +	Reference -
+	21	1
-	1	22
Total	22	23

Statistic	Percent	95 % CI	
		Lower	Upper
Positive Agreement	95.5	77.2	99.9
Negative Agreement	95.7	78.1	99.9

Table 6.5 – *S. aureus* Identification Summary, SN bottles

Analysis: *S. aureus* Identification

SN bottles

KeyPath	Reference +	Reference -
+	44	0
-	1	30
Total	45	30

Statistic	Percent	95 % CI	
		Lower	Upper
Positive Agreement	97.8	88.2	100
Negative Agreement	100	88.4	100

Table 6.6 – Methicillin Resistance Testing Summary, SN bottles

Analysis: Methicillin resistance

SN bottles

KeyPath	Reference +	Reference -
+	20	1
-	1	22
Total	21	23

Statistic	Percent	95 % CI	
		Lower	Upper
Positive Agreement	95.2	76.2	99.9
Negative Agreement	95.7	78.1	99.9

For all evaluations of *S. aureus* identification and determination of resistance and susceptibility, the KeyPath™ MRSA/MSSA Blood Culture Test – BT functioned as intended and the levels of positive and negative agreement observed were as expected.

Substantial Equivalence

The KeyPath™ MRSA/MSSA Blood Culture Test – BT, when used on samples from BACTEC™ Standard/10 Aerobic/F or Standard Anaerobic/F bottles, is as safe and effective as the KeyPath™ MRSA/MSSA Blood Culture Test – BT when used on samples from cleared bottle types (BACTEC™ Plus Aerobic/F and Plus Anaerobic/F). The KeyPath™ MRSA/MSSA Blood Culture Test – BT technological characteristics and principles of operation are unchanged. Other than the addition of bottle types, the intended use is unchanged. The expanded intended use raises no new issues of safety or effectiveness. Performance data demonstrate that the KeyPath™ MRSA/MSSA Blood Culture Test – BT, when used on samples from BACTEC™ Standard/10 Aerobic/F or Standard Anaerobic/F bottles, is as safe and effective as the KeyPath™ MRSA/MSSA Blood Culture Test – BT when used on samples from cleared bottle types (BACTEC™ Plus Aerobic/F and Plus

Anaerobic/F). Thus, the KeyPath™ MRSA/MSSA Blood Culture Test – BT is substantially equivalent when used with additional BACTEC™ bottle types.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

MAR 3 0 2012

MicroPhage, Inc.
c/o Drew Smith, Ph.D.
Chief Science Officer
2400 Trade Centre Ave
Longmont, CO 80503

Re: K120563
Trade/Device Name: KeyPath™ MRSA/MSSA Blood Culture Test-BT
Regulation Number: 21 CFR § 866.2050
Regulation Name: Staphylococcal typing bacteriophage
Regulatory Class: I
Product Code: OUS
Dated: February 24, 2012
Received: February 24, 2012

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

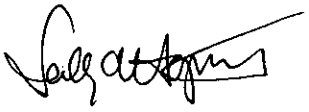
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K120563

Device Name: **KeyPath™ MRSA/MSSA Blood Culture Test – BT**

Indications for Use:

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is a qualitative *in vitro* diagnostic test for the timely identification of *Staphylococcus aureus (S. aureus)* and determination of methicillin susceptibility (MSSA) or methicillin resistance (MRSA) directly from positive blood cultures.

The Test uses bacteriophage amplification to identify the presence of *S. aureus* and assess the phenotypic response of the target organism to cefoxitin, an indicator of oxacillin (a methicillin analog) resistance.

The assay is performed directly on positive blood culture specimens that are determined as Gram Positive Cocci in singles (GPC) or as Gram Positive Cocci in Clusters (GPCC) by Gram stain.

The KeyPath™ MRSA/MSSA Blood Culture Test – BT is performed directly on positive blood culture specimens from BD BACTEC™ blood culture bottles (Plus Aerobic/F, Plus Anaerobic/F, Standard/10 Aerobic/F and Standard Anaerobic/F).

The Test is indicated for use in conjunction with other laboratory and clinical data available to the physician as an aid in the detection of MRSA/MSSA from positive blood cultures.

Subculturing of positive blood cultures is necessary for additional susceptibility test determinations, differentiation of mixed growth and for epidemiological typing

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K120563